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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

[Docket No. 00N–1634]

Public Hearing Before a Public Advisory Committee; Examination of Administrative Record and Other Advisory Committee Records

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its administrative regulations governing the public disclosure of written information for consideration by an advisory committee at an advisory committee meeting. This action would amend the regulations to state that written information for consideration by an advisory committee at a committee meeting is available for public disclosure, whenever practicable, before or at the time of the meeting. FDA is proposing this action to reflect current FDA policy in conformance with applicable law. This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**.

DATES: Submit written comments on the proposed rule by [*insert date 75 days after date of publication in the* **Federal Register**]. If FDA receives no significant adverse comment on the amendment of these regulations within the specified comment period, the agency intends to publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period in the direct final rule ends. The direct final rule will be effective 30 days after publication of the confirmation notice in the **Federal Register**.

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ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Andrea C. Masciale, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Discussion

As described more fully in the related direct final rule, FDA's procedures for the administration of advisory committees are set forth in part 14 (21 CFR part 14). Section 14.75(a)(1) states that unless it is otherwise exempt from disclosure, written information for consideration by the committee at the meeting should be available for public disclosure at the same time it is made available to the committee. FDA finds that this provision for simultaneous disclosure is not required by the Federal Advisory Committee Act (5 U.S.C. app. 2) and that compliance with this provision would be detrimental to the advisory committee process. Therefore, the agency is proposing to amend § 14.75(a)(1) to state that the written information for consideration by an advisory committee at any meeting is available for public disclosure, whenever practicable, before or at the time of the meeting.

II. Additional Information

This proposed rule is a companion to the direct final rule published in the final rules section of this issue of the **Federal Register**. This companion proposed rule and the direct final rule are identical. This companion proposed rule will provide the procedural framework to finalize the rule in the event the direct final rule receives significant adverse comments and is withdrawn. The comment period for this companion proposed rule runs concurrently with the comment period of the direct final rule. Any comments received under the companion proposed rule will be treated as comments regarding the direct final rule.

If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, FDA will publish a confirmation document within 30 days after the comment period ends, and FDA intends the direct final rule to become effective 30 days after publication of the confirmation document. If FDA receives significant adverse comments, the agency will withdraw the direct final rule. FDA will proceed to respond to all of the comments received regarding the rule and, if appropriate, the rule will be finalized under this companion proposed rule using usual notice-and-comment procedures.

For additional information, see the corresponding direct final rule published in the final rules section of this issue of the **Federal Register**. FDA will not provide additional opportunity for comment. A significant adverse comment is one that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment recommending a rule change in addition to this rule will not be considered a significant adverse comment, unless the comment states why this rule would be ineffective without the additional change.

III. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the impacts of this proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this

proposed rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866 and in the other two statutes. This proposed rule is not a significant regulatory action as defined by the Executive order.

Under the Regulatory Flexibility Act, if a rule has a significant impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. The agency has considered the effect that this proposed rule will have on small entities. Because the proposed rule will amend only internal agency procedures, the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation). FDA is not required to prepare a statement of the costs and benefits of this proposed rule because the proposed rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation. The current inflation-adjusted statutory threshold is $110 million.

V. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the proposed rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

VI. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this proposal by [*insert date 75 days after date of publication in the* **Federal Register**]. This comment period runs concurrently with the comment period for the direct final rule; any comments received will be considered as comments regarding the direct final rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. In the event the direct final rule is withdrawn, all comments received will be considered comments on this proposed rule.

List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 14 be amended to read as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

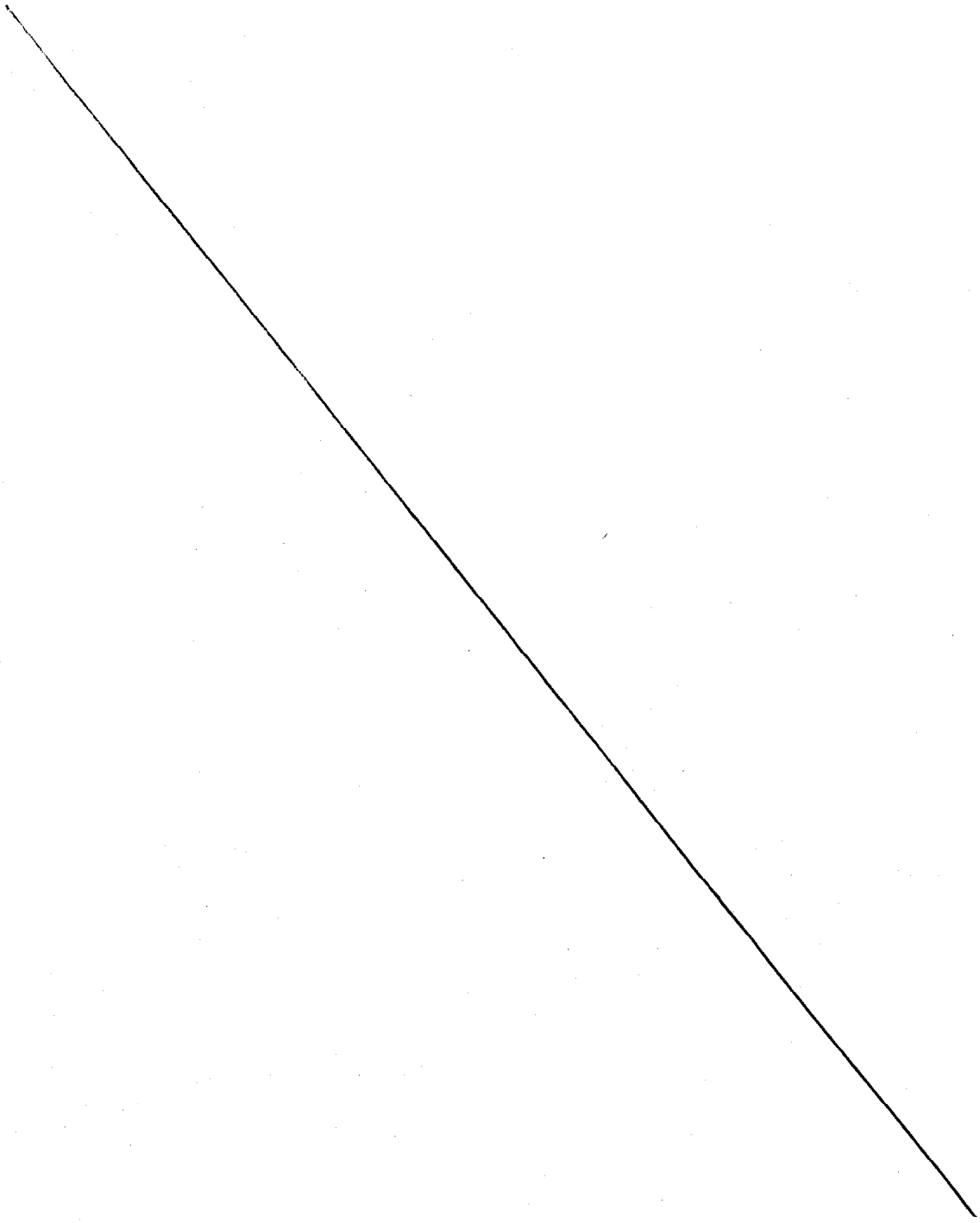
1. The authority citation for 21 CFR part 14 is revised to read as follows:

Authority: 5 U.S.C. App. 2; 15 U.S.C. 1451–1461; 21 U.S.C. 41–50, 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

2. Section 14.75 is amended by revising paragraph (a)(1) to read as follows:

§ 14.75 Examination of administrative record and other advisory committee records.

(a) * * *



(1) The written information for consideration by the committee at any meeting: Whenever practicable, before or at the time of the meeting.

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Dated: 12/29/00
December 29, 2000.

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 01–???? Filed ??–??–01; 8:45 am]

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